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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,477	04/15/2004	Fabio Soldati	01-1490	8137

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EXAMINER	
MAEWALL, SNIGDHA	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
08/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/825,477	SOLDATI ET AL.	
	Examiner	Art Unit	
	Snigdha Maewall	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 5-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2 and 5-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

1. Receipt of Applicant's arguments and amended claims filed on 05/05/08 is acknowledged.

Claims 3-4 remain cancelled.

Claims **1-2 and 5-20** are under prosecution.

The following rejections of record are maintained.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-2 , 5-9 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/53777 ('777) in view of deVries et al. (US Patent No. 6,495,177 B1).

('777) discloses a composition comprising the following minerals and vitamins recommended for pregnant and lactating women: calcium, magnesium, iron, copper, zinc, iodine, vitamin A, vitamin E, vitamin B1, vitamin B2, vitamin B6, vitamin B12, vitamin C, folic acid, niacin (page 2, paragraph 6 and claim 2). DHA is disclosed on (page 4, paragraph, 4). ('777) further discloses that the composition can be in the form of pill, capsule, tablet, chewable candies form (page 6, paragraph, 6). ('777) does not teach the specific weight ratios of various components as claimed. However, with respect to the weight ratios of various components, it is the examiners position that optimization of such a parameter is within the purview of a skilled artisan by doing experimental manipulation absent evidence to the contrary. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

('777) does not teach problems associated with calcium in chewable multi vitamin tablet. deVries teaches an orally administrable nutritional supplement which is highly palatable, such as a chewable prenatal vitamin/mineral supplement. The supplement is preferably made in the form of a tablet that, upon chewing, dissolves rapidly in the mouth. The tablet is particularly suitable for administration of vitamins and minerals to women during pregnancy. The invention also includes methods of making and using such supplements (abstract). The invention comprises vitamins, carotene, iron, flavorants etc. Calcium is excluded from the solid dosage form or if present is in less than therapeutic amount DeVries further teaches that preferred absence of calcium from the tablet ensures

minimal interference of iron absorption by minerals present in the tablet. (see column 7, lines 5-53 and column 11 ,lines 28-35).

It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to exclude calcium from the composition forwarded by ('777) because DeVries teaches that absence of calcium from the tablet ensures minimal interference of iron absorption by minerals. A skilled artisan would thus have been motivated to formulate a composition comprising vitamins and minerals as claimed in the instant invention with an expectation of obtaining a dietary composition which would supplement the needs of pregnant women with a reasonable success.

Response to Arguments

4. Applicant's arguments filed 11/21/2007 have been fully considered but they are not persuasive.

Applicant argues that '777 reference teaches nutritional supplement comprising calcium and the reference also teaches the importance of calcium in pregnant women and DeVries teaches exclusion of calcium. Therefore, the combination of the two references would not teach the claimed invention since the references are not sufficient to establish *prima facie* case of obviousness and thus the rejections shall be withdrawn.

Applicants arguments are not persuasive. Applicant is doing piecemeal analysis of the prior art cited. Applicant is emphasizing the preferred embodiments of the references cited in the arguments, however, the prior art is evaluated for the full scope of what it reasonably suggests or what would have been obvious to the one of ordinary skilled in

the art in light of the teachings of the prior art. Prior art teaches other essential components in addition to calcium. ('777) discloses a composition comprising the following minerals and vitamins recommended for pregnant and lactating women: calcium, magnesium, iron, copper, zinc, iodine, vitamin A, vitamin E, vitamin B1, vitamin B2, vitamin B6, vitamin B12, vitamin C, folic acid, niacin (page 2, paragraph 6 and claim 2). De Vries teaches absence of calcium from the tablet in ensuring minimal interference of iron absorption by minerals present in the tablet. (See column 7, lines 5-53 and column 11, lines 28-35). In view of the combination of the teachings of the two references one skilled in the art would have been motivated to exclude calcium from the composition forwarded by ('777) because DeVries teaches that absence of calcium from the tablet ensures minimal interference of iron absorption by minerals. Applicant is arguing references individually; one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

5. Claims 10-13 and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/53777 ('777) in view of de vries et al. (US Patent No. 6,495,177 B1) and further in view of Uiterwaal et al. (US patent No. 4,710,387). The teachings of ('777) and devries have been discussed above. ('777) and De Vries do not teach molybdenum, chromium and iodine in the composition.

Uiterwaal et al. teaches nutritional supplement preparation for pregnant and breast-feeding women based on milk constituents for pregnant and breast feeding women comprising iodine, calcium, phosphorus, various vitamins, chromium and molybdenum, niacin and folic acid etc. (see Table A in column 7, claim 5 and 8). Since the composition provides nutritional supplement to pregnant and breast feeding women, it would have been obvious to the one of ordinary skilled in the art at the time the invention was made to incorporate nutrients such as iodine, chromium and molybdenum in the composition forwarded by ('777). A skilled artisan would have made formulation comprising molybdenum, chromium, iodine, vitamins, minerals, niacin, folic acid and DHA with a reasonable expectation of success.

With respect to the weight ratios of various components and amounts, it is the examiners position that optimization of such parameters are within the purview of a skilled artisan by doing experimental manipulation. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable range by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Response to Arguments

6. Applicant's arguments filed 05/05/08 have been fully considered but they are not persuasive.

Applicant argues that Uiterwall does not cure the deficiencies of the two references discussed above; therefore the rejections shall be withdrawn. Applicant's arguments are not persuasive and the response to applicant's arguments has been discussed above.

7. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/53777 ('777) in view of de vries et al. (US Patent No. 6,495,177 B1) and further in view of Uiterwaal et al. (US patent No. 4,710,387) and DRUGDEVELOPMENT AND INDUSTRIAL PHARMACY, 12(8&9), 1133-1144 (1986) Robert F. Jimerson.

The teachings of ('777), devries and Uiterwaal et al. have been discussed above. The references do not teach oblong gelatin capsule. However, Robert F. Jimerson discloses soft gelatin capsule. Robert F. Jimerson further disclose that because of their special properties and advantages, soft gelatin capsules are employed for a wide variety of uses in pharmaceutical industries and are produced in a variety of shapes, sizes, and colors. Their current applications primarily include, oral dosage forms, suppositories and topical products (see page 1134, paragraph 2 and 3).
It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to make gelatin capsule of the oblong shape since the article teaches that gelatin capsules bear special properties and advantages in pharmaceutical compositions. A skilled artisan would have made gelatin capsule comprising various nutritional components comprising vitamins, minerals, folic acid, biotin and niacinamide with a reasonable expectation of success.

Response to Arguments

8. Applicant's arguments filed 05/05/08 have been fully considered but they are not persuasive.

Applicant argues that the claim depends on claim 10 which recites the limitation of the dosage form being "non chewable" and thus the reference of Jimerson would not make it obvious to one skilled in the art to form the claimed non chewable tablet. This argument is not persuasive because Jimerson teaches that soft gelatin capsules are employed for a wide variety of uses in pharmaceutical industries as stated in the rejection above. Furthermore as stated above, claim 10 does not recite the specific amounts and proportions of various components, in the absence of such the invention as whole would have been obvious to one of ordinary skilled in the art at the time of invention.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/

Examiner, Art Unit 1612

/Gollamudi S Kishore, Ph.D/

Primary Examiner, Art Unit 1612